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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,291	11/28/2006	Pascale Gaillard	285380US0PCT	6383
22850	7590	09/29/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER BALASUBRAMANIAN, VENKATARAMAN	
			ART UNIT	PAPER NUMBER
			1624	
			NOTIFICATION DATE	DELIVERY MODE
			09/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/571,291	Applicant(s) GAILLARD ET AL.	
	Examiner /Venkataraman Balasubramanian/	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/9/2006, 6/1/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The preliminary amendment, which included amendment to claims 1-10 and addition of new claims 11-14, filed on 3/9/2006, is made of record. Claims 1-14 are now pending.

Information Disclosure Statement

References cited in the Information Disclosure Statements, filed on 3/9/2006 & 6/1/2006, are made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Recitation of "derivative" in claims 1-14 renders these claims indefinite as the term derivative implies more than what is being positively recited therein. Note a derivative can be any organic core or group bearing the benzothiazole core, thus the structural make-up of the genus remains unknown. A benzothiazole compound is suggested.
2. Recitation "as well as its tautomers, its geometrical isomers, its optically active forms as enantiomers, diastereomers and its racemate forms, as well as pharmaceutically acceptable salts thereof" in claim 1 renders claim 1 and dependent claims indefinite as it is not clear whether claim 1 is compound claim or a composition

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claims with its tautomers, its geometrical isomers, its optically active forms as enantiomers, diastereomers and its racemate forms, and pharmaceutically acceptable salts. Note Markush choices should be in alternate form and in singular.

3. Claim 1 and its dependent claims 2-14 are indefinite as it is not clear whether claim 1 is a compound claim or a method of use claim. The preamble of claim appears to imply it is a compound claim but the last three lines of the claim refers to treating metabolic disorders. If it is a method of use claim, claim 1 and its dependent claims are still indefinite as claim 1 does not recite to whom the compound to be administered and what is the effective amount.

4. Recitation of "sulfonyl" in claim 1 renders claim 1 and the dependent claims 2-14 indefinite as a sulfonyl is a divalent group and what else is appended to this group to meet the valence requirement is unclear.

5. Recitation of recitation of transitional term "comprising" in claims 13 and 14 renders these claims indefinite as the term is open-ended and can embrace additional substituents not positively recited therein. Note according to MPEP, The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., >Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.");< Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named

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elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 11, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Halazy et al., WO 01/47920.

Halazy et al., teaches several benzazole compounds useful for treating disorder of immune system cancer, which include instant compounds. See page 9, formula I and note definition of the X, G, L, R¹, and R². Note when X is S, G= pyrimidinyl with L substituents, with given definition of other variable choices, the compounds taught by Halazy et al., include instant compounds. See pages 9-24 for details of the preferred embodiments, species and process of making these compounds. See entire document. Particularly, see pages 28-54, for examples of compounds made.

Claims 1-8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaillard et al., WO 03/091249.

Gaillard et al., teaches several benzothiazole compounds useful for treating

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ischemic disorders, which include instant compounds. See page 3, formula A and note definition of the X, G, R¹, and R². Note when X is S, G= pyrimidinyl with substituents, with given definition of other variable choices, the compounds taught by Gaillard et al., include instant compounds. See pages 3-17 for details of the preferred embodiments, species and process of making these compounds. See entire document. Particularly, see pages 20-29, for examples of compounds made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Halazy et al., WO 01/47920.

Teachings of Halazy et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Halazy et al., teaches several benzazole compounds useful for treating disorder of immune system cancer, which include instant compounds. See page 9, formula I and note definition of the X, G, L, R¹, and R². Note when X is S, G= pyrimidinyl with L substituents, with given definition of other variable choices, the compounds taught by Halazy et al., include instant compounds. See pages 9-24 for details of the preferred embodiments, species and process of making these compounds. See entire document. Particularly, see pages 28-54, for examples of compounds made. Although Halazy et al. teaches several benzothiazole compounds, Halazy et al., does not exemplify all the compounds of genus of compound of formula I shown in page 9, wherein X=S. But Halazy et al., teaches equivalency of alternate choices of all variables including X, with the compounds taught in pages 9-54 with those generically claimed in page 9.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make various compounds of formula I as permitted by the reference using teachings of Halazy et al., and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1-8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaillard et al., WO 03/091249.

Teachings of Gaillard et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Gaillard et al., teaches several benzothiazole compounds useful for treating ischemic disorders, which include instant compounds. See page 3, formula A and note definition of the X, G, R¹, and R². Note when X is S, G= pyrimidinyl with substituents, with given definition of other variable choices, the compounds taught by Gaillard et al., include instant compounds. See pages 3-17 for details of the preferred embodiments, species and process of making these compounds. See entire document. Particularly, see pages 20-29, for examples of compounds made.

Although Gaillard et al. teaches several benzothiazole compounds, Gaillard et al., does not exemplify all the compounds of genus of compound of formula A shown in page 3, wherein X=S. But Gaillard et al., teaches equivalency of alternate choices of all variables with the compounds taught in pages 20-29 with those generically claimed in page 3. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to make various compounds of formula A as permitted by the reference using teachings of Gaillard et al., and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 11, 12 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 9 of U.S. Patent No. 7,314,878. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound and composition embraced in the instant claims are also embraced in the compound and composition claims of the US 7,314,878. Note the intended use recited in the instant claims are not given any weight as a compound is a compound irrespective of its intended use.

See *Intirtool, LTD. V. Texar Corp.*, 70 USPQ2D 1780. Note court held that "In general, a claim preamble is limiting if recites essential structure or steps or if it is necessary to give" life, meaning, and vitality to claim.'.... However, if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not effect the structure or steps of the claimed invention,' the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish

the claimed invention from the prior art.”

Instant claim is a compound claim and is clearly defined by a structure namely a benzothiazole core with a side chain bearing pyrimidine. Omission of the attributes to the compound of genus of claim 1 would not alter the structure of these compounds.

Thus, one trained in the art would be motivated to make the compounds of the genus taught therein and arrive at instant compounds and expect these compounds have the use taught therein.

Claims 1-8, 11, 12 and 14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7,259,162. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound and composition embraced in the instant claims are obvious over compounds of claims 1-5 of the US 7,259,162. Thus, one trained in the art would be motivated to make the compounds of the genus taught therein and arrive at instant compounds and expect these compounds have the use taught therein. Note the intended use recited in the instant claims are not given any weight as a compound is a compound irrespective of its intended use.

See *Intirtool, LTD. V. Texar Corp.*, 70 USPQ2D 1780. Note court held that “ In general, a claim preamble is limiting if recites essential structure or steps or if it is necessary to give” life, meaning, and vitality to claim.’.... However, if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not effect the structure or steps of the claimed invention,’ the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish

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the claimed invention from the prior art.” Instant claim is a compound claim and is clearly defined by a structure namely a benzothiazole core with a side chain bearing pyrimidine. Omission of the attributes to the compound of genus of claim 1 would not alter the structure of these compounds.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624

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